COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27-01-2004
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NOT FOR PUBLICATION

**COMMISSION DECISION**

**of 27-01-2004**

**amending the marketing authorisation for "Tenecteplase Boehringer Ingelheim Pharma GmbH & Co. KG - tenecteplase", a medicinal product for human use, granted by Decision C(2001)286**

**(Text with EEA relevance)**

ONLY THE GERMAN TEXT IS AUTHENTIC

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**amending the marketing authorisation for "Tenecteplase Boehringer Ingelheim Pharma GmbH & Co. KG - tenecteplase", a medicinal product for human use, granted by Decision C(2001)286**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 8(3) thereof,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 25 July 2003 under Article 6(1) of Commission Regulation (EEC) No 542/95,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[3], and in particular Article 6(10) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products on 25 September 2003,

Whereas:

(1) An examination of the variations to the terms of the marketing authorisation for the medicinal product "Tenecteplase Boehringer Ingelheim Pharma GmbH & Co. KG - tenecteplase", entered in the Community register of medicinal products under Nos EU/1/00/168/001-006 and authorised by Commission Decision

[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).
[2] OJ L 55, 11.3.1995, p. 15, as amended by Regulation (EC) No 1069/98 (OJ L 153, 27.5.1998, p. 11).
[3] OJ L 159, 27.6.2003, p. 24.

C(2001)286 of 23 February 2001, has shown that the product still complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) The application to modify the authorisation and to amend Decision C(2001)286 accordingly should be accepted.

HAS ADOPTED THIS DECISION:

*Article 1*

Decision C(2001)286 is amended as follows:

1. Annex I is replaced by the text set out in Annex I to this Decision;

2. Annex III B is replaced by the text set out in Annex II to this Decision.

*Article 2*

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 27-01-2004

*For the Commission*
*Erkki LIIKANEN*
*Member of the Commission*

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).